



OCT 15 2007

J. Eric Thies
Merck & Co., Inc.
Patent Department
PO Box 2000
Rahway NJ 07065-0907

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,719,147

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,719,147, claims of which cover the human drug product EMEND® (aprepitant), a pharmaceutical composition comprising EMEND® (aprepitant) and a method of using EMEND® (aprepitant), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,022 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,022 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of August 3, 2006, (71 Fed. Reg. 44033). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2332 - 649) + 181 \text{ days} \\ &= 1,022 \text{ days (2.8 years)}\end{aligned}$$

Since the regulatory review period began May 10, 1996, before the patent issued (February 17, 1998), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 10, 1996, to and including February 17, 1998, is 649 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,719,147
Granted:	February 17, 1998
Original Expiration Date ¹ :	June 29, 2012

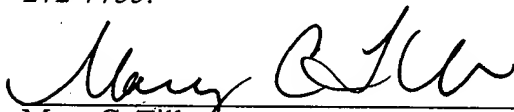
¹Subject to the provisions of 35 U.S.C. § 41(b).

Applicant: Conrad P. Dorn, et al.
Owner of Record: Merck & Co., Inc.
Title: MORPHOLINE AND THIOMORPHOLINE
TACHYKININ RECEPTOR ANTAGONISTS
Product Trade Name: EMEND® (aprepitant)
Term Extended: 1,022 days
Expiration Date of Extension: April 17, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7755
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: EMEND® (aprepitant)
FDA Docket No.: 2003E-0418